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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/121,239	07/23/1998	RICHARD C. HARVEY	GP091-02.UT	3098

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EXAMINER
SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/121,239	HARVEY ET AL.	
	Examiner	Art Unit	
	Mary M. Schmidt	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10,12 and 14-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-10,12 and 14-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 1998* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/09/2002 has been entered.

Specification

2. In the amendment filed 11/12/02, the proposed amendments to the specification on pages 1-2 of the amendment have not been entered since they are not in the proper format. They are not in compliance with the new Rule 121 practice which requires that the clean copy be identical to the marked up copy except that the marked up copy has the additions and subtractions. In view of this the following informality stands:

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 since the brief description of the drawings (Figures 2 and 3) on page 13 of the specification does not reference the sequences in the figures by SEQ ID NO. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). A complete response to the instant Office action must include correction of the informalities.

Drawings

4. The drawings filed 07/23/98 have approved by an Official draftsman.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5-10, 12, 14-18 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims as amended comprise use of "abl-specific", "bcr-derived" and "bcr-specific" primers as well as primers "derived from a bcr sequence" and "derived from an abl sequence". The specification as filed does not further define the metes and bounds of such primers so that one of skill in the art would be able to immediately envisage the claimed sequences. The specification as filed teaches on page 2, lines 8-11, that a ""breakpoint junction" of a translocation refers to the joining point of sequences derived from normally separated chromosomal locations." So, while it appears that the amendments to the claims are considered to be interpreted that the abl-specific primer binds only the abl region of the bcr-abl translocation,

and the bcr-specific primer binds only the bcr region of the bcr-abl translocation, the specification as filed does not clearly define this as such. Therefore, it would be more clear to use the language in the specification, and to define the spacial orientation of the primer based on the location of the break-point junction for instance. In the case of the bcr-"derived" sequence, the specification is further unclear since it is not clear whether this primer may also include regions from the abl sequence, and thus span the translocation junction. The specification as filed further teaches in Figure 1C a primer that spans the translocation junction. Without further guidance as to what sequence characteristics distinguish the "derived" and "specific" primer sequences in the claims as amended, one of skill of skill in the art would not have recognized that applicant was in possession of a representative number of species of any such primer at the time the invention was made.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 19 and 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Qiagen Oligotex Direct Protocol for isolation of PolyA+ mRNA from cytoplasm of cultured cells (Qiagen Oligotex Direct mRNA Handbook protocol, dated November 1994, pages 1-51).

Qiagen teaches a method for preparing a sample containing RNA suitable for amplification (they teach purification of RNA from cultured cells), via the steps of (a) providing a biological sample comprising unpurified RNA (they teach starting with cells from cell culture), mixing the biological sample with a solution consisting essentially of a buffer at a pH of about 6.5 to about 8.5, about 150mM to about 1M or soluble salt, and about 0.5% to about 1.5% (v/v) of a non-ionic detergent, to produce a solution containing released RNA (they teach use of the OLC buffer on page 48 Appendix A, having a pH of 8.0, 140 mM of NaCl and 1.5mM of $MgCl_2$ soluble salt, and 0.5% of the non-ionic detergent Nonidet P-40, mixing the solution containing released RNA with a solid support to which is joined an immobilized oligonucleotide comprising a nucleotide base sequence which forms a stable immobilized oligonucleotide: RNA hybridization complex under hybridization conditions (they teach on page 39, step 4, hybridization of the RNA with an oligo dT30 linked to the Oligotex particles and the poly-A tail of themRNA), separating the hybridization complex joined to the solid support from unhybridized sample components (they teach pelleting the oligotex:mRNA complex by centrifugation and removal of the supernatant containing the unhybridized sample components), and washing the hybridization complex joined to the solid support with a solution having sufficient salt concentration to maintain the hybridization complex, thereby not requiring

extraction using reagents such as phenol or chloroform to prepare RNA (they teach resuspension of the oligotex:RNA pellet in the buffer OW1 and OW2 (page 36) for final suspension of the RNA product). The methods taught by Qiagen may be applied to whole cells and tissues (page 6).

9. Claims 1-3, 6-10, 12, 14-18 and 21-26 are now considered to be free of the prior art since the closest prior art, Sooknanen et al. cited previously taught only use of bcr-abl hybrid primers, and not abl or bcl specific primers.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
February 26, 2003

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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